REMARKS

Claims 19, 54-57, 59-63 and 65-82 were pending in the present application. Claims 19, 54-57, 59-63 and 65-82 have been canceled without prejudice and claims 83-104 have been added. Therefore, claims 83-104 will be pending upon entry of the present amendment. Support for the new claims can be found, for example, in the previously pending claims and at page 49, lines 24-26, at page 56, line 31 to page 57, line 7, at page 58, line 29 to page 59, line 33, at page 60, lines 10-23, at page 65, line 12 to page 66, line 2 and at page 91, line 30 to page 92, line 5. No new matter has been added.

Applicants additionally wish to thank the Examiner for acknowledging receipt of the Supplemental Information Disclosure Statement (IDS) which was filed by Applicants on July 25, 2002 and for acknowledging that the publications listed therein will be considered by the Examiner.

Rejection of Claims 19, 54-57, 59-63 and 65-82 Under 35 U.S.C. § 112, ¶1

Claims 19, 54-57, 59-63 and 65-82 are rejected under 35 U.S.C. § 112, first paragraph, as "failing to comply with the enablement requirement."

Specifically, the Examiner asserts that only isolated proteins comprising SEQ ID NO:12 and SEQ ID NO:2 meet the written description guideline. Applicants respectfully traverse this rejection.

"The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *See Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000). In particular, an adequate description can be made by disclosing identifying characteristics, such as complete or partial structure, functional characteristics, or physical and/or chemical properties. "Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, para. 1 'Written Description' Requirement", "66 Fed. Reg. 1099, 1106 (January 5, 2001). An Applicant may also rely upon

functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id.*

Newly pending claim 83 and dependent claims 84-93 recite that the polypeptides of the claimed invention be at least 95% identical to the amino acid sequence of SEQ ID NO:2, wherein the polypeptides further have protease activity. The recitation of at least 95% sequence identity is a very predictable structure of the sequences encompassed by the claimed invention. The Examiner is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. 66 Fed. Reg. 1099, 1106 (2001). Applicants submit that the knowledge and level of skill in the art would allow a person of ordinary skill to envision the claimed invention, *i.e.*, a method using a sequence having at least 95% sequence identity to the sequence set forth in SEQ ID NO:2.

Furthermore, the description of a claimed genus can be by structure, formula, chemical name, or physical properties. *See Ex parte Maizel*, 27 USPQ2d 1662, 1669 (B.P.A.I. 1992), *citing Amgen v. Chugai*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). A genus of DNAs may therefore be described by means of a recitation of a representative number of DNAs, defined by nucleotide sequence, falling within the scope of the genus, or by means of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997); *see also* Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (2001). The recitation of a predictable structure of at least 95% sequence identity to SEQ ID NO:2 is sufficient to satisfy the written description requirement.

As indicated above, an applicant may also rely upon functional characteristics in the description, provided there is a correlation between the function and structure of the claimed invention. *Id., citing Lilly* at 1568. The claimed methods recite the use of a polypeptide having

protease activity. Thus, the claims provide a functional characterization of the sequences claimed in the genus.

Example 14 of the Revised Interim Written Description Guidelines is directed to a generic claim: a protein having at least 95% sequence identity to the sequence of SEQ ID NO:3, wherein the sequence catalyzes the reaction A to B. The Training Materials concludes that the generic claim of Example 14 is sufficiently described under § 112, first paragraph, because 1) "the single sequence disclosed in SEQ ID NO:3 is representative of the genus" and 2) the claim recites a limitation requiring the compound to catalyze the reaction from A to B. The Guidelines conclude that one of skill in the art would recognize the necessary common attributes possessed by the members of the genus.

Following the analysis of Example 14, Applicants submit that newly pending claim 83 and dependent claims 84-93 satisfy the written description requirements of § 112, first paragraph. Specifically, the claims of the present invention encompass the use of sequences having at least 95% sequence identity to the sequence of SEQ ID NO:2, wherein the sequence of the claimed invention encodes a polypeptide having protease activity. As in Example 14, the present specification discloses the amino acid sequence of SEQ ID NO:2, and the currently pending claims recite a limitation requiring the polypeptide to have a specific function (*i.e.*, a protease activity).

Consequently, the sequences of the claimed invention are defined by relevant identifying physical and chemical properties. In fact, the common attributes or features of the elements possessed by the members of the genus is that the polypeptides have protease activity and that they share at least 95% sequence identity to the disclosed amino acid sequence of SEQ ID NO:2.

In summary, the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Applicants submit that the relevant identifying physical and chemical properties of the disclosed genus would be clearly recognized by one of skill in the art and consequently, the Applicants have disclosed the necessary common attributes or features of the elements possessed by the members of the genus. Accordingly, Applicants respectfully request

reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 19, 54-57, 59-63 and 65-82.

Rejection of Claims 63 and 72-82 Under 35 U.S.C. § 112, ¶1

Claims 63 and 72-82 are rejected under 35 U.S.C. § 112, first paragraph as "failing to comply with the enablement requirement."

Specifically, the Examiner rejected these claims on the basis that the hydrolysis activity could not be relied upon to determine the effect of interaction between the polypeptides and a compound. Applicants respectfully traverse this rejection, however in an effort to expedite prosecution of the present application, Applicants have canceled claims 63 and 72-82, thereby rendering the 35 U.S.C. § 112, first paragraph rejection over claims 63 and 72-82 moot.

Rejection of Claims 69-92 Under 35 U.S.C. § 112, ¶1

Claims 69-92 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants note that the Examiner rejected claims 69-92, however since the previously pending claim set did not include claims beyond claim 82, Applicants will consider that the rejection was meant for claims 69-82.

Specifically, the Examiner rejected claims 69-82 for the recitation of "at least one but less than 5 amino acid residues from the amino acid sequence of SEQ ID NO:2", asserting that this limitation added new matter. Applicants respectfully traverse this rejection, however in an effort to expedite prosecution of the present application, Applicants have canceled claims 69-82, thereby rendering the 35 U.S.C. § 112, first paragraph rejection over claims 69-82 moot.

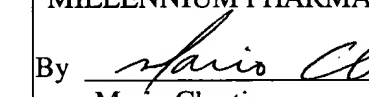
CONCLUSION

In view of the amendments and remarks made herein, Applicants respectfully submit that the rejections presented by the Examiner are now overcome and that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is believed that this paper is being filed timely and that a three month extension of time is required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

November 22, 2004	MILLENNIUM PHARMACEUTICALS, INC. By  Mario Cloutier Limited Recognition Under 37 C.F.R. §10.9(b) 40 Lansdowne Street Cambridge, MA 02139 Telephone – (617) 577-3522 Facsimile – (617) 551-8820